REMARKS

Claims 1, 4-5, 13-20, 32-41, 43-44, and 48-57 remain pending in the application. Claims 13-20 and 33-40 were previously withdrawn. Claims 2, 3, 21-31, and 45-47 were previously canceled. Claims 6-12, and 42 are hereby canceled without prejudice or waiver of the right to pursue the subject matter of said claims in this or another application. Claims 1 and 48 have been amended. New claims 53-57 have been added. All other claims remain unchanged. Reconsideration of the pending claims is respectfully requested.

Applicants acknowledge with appreciation Examiner's indication of the allowability of claims 48-52 if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have amended claim 48 as suggested.

Claim 1 was amended to include the subject matter of claims 6-12 and 42. Applicants submit that no new subject matter has been added by way of amendment and support for the added subject matter is found in the original claims as indicated.

New claim 53 further defines the amount of licofelone present in the core and external coat and also specifies an overall release profile for licofelone from the device. Applicants submit that no new subject matter has been added by way of amendment and support for the added subject matter is found in the specification as originally filed (Examples 2 and 4, pg. 9, lines 8-12).

New claim 54, which depends from and includes the subject matter of claim 53, further defines the amount of osmotic agent, osmopolymer, water soluble polymer and disintegrant present in the core. Applicants submit that no new subject matter has been added by way of amendment and support for the added subject matter is found in the specification as originally filed (Example 4).

New claim 55, which depends from and includes the subject matter of claims 53 or 54, further defines the release profile of licofelone from the core and the maximum time period of release of the licofelone from the drug-containing coat. Applicants submit that no new subject matter has been added by way of amendment and support for the added subject matter is found in the specification and claims as originally filed (claims 6-12, and 42; pg.8, ln. 26 to pg. 11, ln. 26; pg. 4, ln. 17-19).

New claim 56, which depends from and includes the subject matter of claim 55 further requires an inert water soluble and/or erodible coating. Applicants submit that no new subject

matter has been added by way of amendment and support for the added subject matter is found in the specification and claims as originally filed (Examples 2 and 4; pg. 3, ln. 23-24; pg. 4, ln. 13-15; pg. 13, ln. 1 to pg. 16, ln. 24; original claim 4).

New claim 57, which depends from and includes the subject matter of claim 55, specifies that the weight of the external coat is about 25% wt. of the osmotic device. Applicants submit that no new subject matter has been added by way of amendment and support for the added subject matter is found in the claims as originally filed (claim 12)

Claims 1, 4-12, 32 and 41-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 4,783,337 to Wong et al. and U.S. 6,352,721 (PHUS-15) to Faour et al. in view of U.S. 5,681,584 to Savastano et al. and WO 2003/097041 to Smolka et al. Examiner argues that the '337 and '721 Patents disclose an osmotic device possessing most or all of the elements of the instant claims, with the exception that they do not disclose administration of licofelone via an osmotic device. Examiner then relies upon the '584 Patent as disclosing an osmotic device having a 5-lipoxygenase inhibitor in the core and upon the '130 Publication as suggesting a variety of different dosage forms that provide a continuous or extended release of ML3000 (licofelone). Insofar as it may apply to the present claims, this rejection is traversed.

Applicants respectfully submit that the prophetic combination still fails to provide any motivation to prepare an osmotic device having the particular release profiles specified for licofelone as it is released from the device overall, the core and from the drug-containing coat (claim 1). Applicants assume that Examiner considers Applicants' specification of the release profile as being arbitrary. However, the specified release profile should result in an osmotic device possessing an unexpectedly favorable clinical profile as compared to another prophetic osmotic device releasing licofelone from the core for a period of less than 12 hours. Moreover, the inclusion of a loading dose (drug-containing coat) with the specified release profile for licofelone is not disclosed or suggested in the art specifically for licofelone. The necessity of the overall release profile for licofelone (the release profile obtained by release of licofelone from the core and the drug-containing coat) specifically is not suggested in the art of record taken individually or in combination.

Accordingly, Applicants respectfully submit that this rejection has been overcome and request that it be withdrawn.

With regard to new claims 53-57, Applicants respectfully submit that said claims are patentable over the prophetic combination of references of record. New claim 53 specifies an osmotic device comprising a core (containing licofelone, 150-600 mg) surrounded by a semipermeable membrane (having at least one preformed passageway) which is then surrounded by a drug-containing water soluble and/or erodible coat (containing licofelone 50-200 mg), wherein licofelone is released from the device according to a specified release profile. The charge of licofelone in the coating serves as a loading dose to rapidly increase a subject's licofelone plasma concentration and rapidly provide a therapeutic benefit. The charge of licofelone in the core serves to maintain the plasma concentration in the subject above a minimum therapeutic threshold for an extended period of time. The specific overall release profile, provided by the specified amount of licofelone released during a specified period of time after administration, is such that the intended therapeutic threshold can be achieved. Claim 54 specifies the amounts for components present in the core and the drug-containing coat in order to provide a specific embodiment of an osmotic device that delivers licofelone according to the claimed release profile. The prophetic combination of art of record does not suggest an osmotic device having the specified components and amounts thereof to provide the specified release profile. The specific release profile provides a balance between the rate of plasma clearance of licofelone, its rate of absorption by a subject following release from the osmotic device, and the rate of initiation and maintenance of the desired therapeutic benefit to be achieved in the subject. New claim 55, which depends from and includes the subject matter of claim 53 or 54, further defines the overall release profile of licofelone from the osmotic device, and/or from the external coat. New claim 56, which depends from and includes the subject matter of claim 55, requires an inert water soluble and/or water erodible coating between the semipermeable membrane and the drug-containing coating. New claim 57, which depends from and includes the subject matter of claim 55, specifies that the weight of the external coat is about 25% wt. of the osmotic device.

It is Applicant's belief that the claimed release profile results in a therapeutic benefit different than what would be achieved by another device having a different release profile. Without any motivation to provide an osmotic device having the specifically claimed release profile, the prophetic combination of references fails to obviate the invention as claimed.

Reconsideration of the claims as now pending is requested.

Pending allowance of the claims, Applicants respectfully request reinstatement and reconsideration of the previously withdrawn claims.

Applicants have made a diligent effort to advance the prosecution of the application by amending the claims and presenting arguments in support of patentability. In view of the above, Applicants submit that the claims are in form for allowance. An early notice of allowance thereof is requested.

Respectfully submitted,

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